

**REMARKS**

The Examiner is thanked for the due consideration given the application. The specification has been amended to insert headings, to add a Field of the Invention, and to insert a paragraph corresponding to the wording of claim 10.

Claims 1-5 and 8-19 are pending in the application. Claims 12-19 are newly presented. Claim 4 has been amended to improve the language. Support for the amendments to claims 1 and for new claims 12-14 can be found at page 3 of the specification. New claims 15-19 generally recite subject matter found in the previous claims.

No new matter is believed to be added to the application by this amendment.

**The Specification**

The specification has been objected to as failing to provide proper antecedence to claim 10. The specification has been amended to insert a paragraph that gives full antecedence to claim 10.

**Claim Objections**

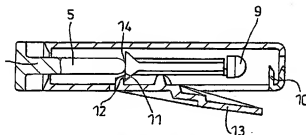
Claim 4 has been objected to as failing to have full antecedent basis. Claim 4 has been amended to have full antecedent basis.

**Rejections Over MORITA**

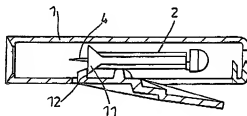
Claims 1, 2, 4, 5, 8, 10 and 11 have been rejected under 35 USC §102(b) as being anticipated by MORITA (U.S. Patent

5,628,765). Claims 3 and 9 have been rejected under 35 USC §103(a) as being unpatentable over MORITA. These rejections are respectfully traversed.

The present invention pertains to a blood sampling device that is illustrated, by way of example, in Figures 5 and 6 of the application, which are reproduced below.



**Fig. 5**



**Fig. 6**

In the present invention, the cap 5 is releasably attached to the lancet 2 adjacent the needle 4 and extends from its attachment to the lancet to pass through an opening in the housing of the device, the cap 5 and housing 1 cooperating so that the cap 5 holds the lancet 2 against movement relative to the housing 1.

Claim 1 of the present invention recites: *"the cap being twistable to release the at least one locating member from the at least one cooperating feature and from the lancet, the at least one cooperating feature such that the cap can be detached from the housing and from the lancet."*

That is, in the claimed device, the cap is releasably attached to the lancet adjacent the needle and extends from its attachment to the lancet to pass through an opening in the housing of the device, the cap and housing cooperating so that the cap holds the lancet against movement relative to the housing. While not explicitly stated in the claim it is also implicit that the cap it is also itself held against movement relative to the housing. The cap is twistable to release (a) its attachment to the housing and (b) its attachment to the lancet. See claim 12.

MORITA pertains to a lancet assembly. The Official Action refers to Figures 12 and 13 of MORITA, which are reproduced below.

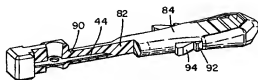


FIG. 12

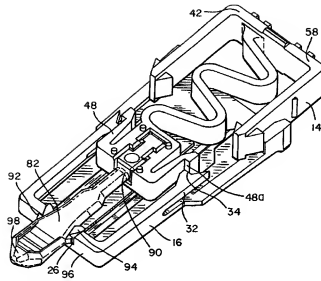


FIG. 13

In the arrangement of MORITA, a lancet is provided with a molded cap, which is designed to be pulled off axially, with the lancet cap being provided with two lateral projections 92, 94 which are designed to be slightly wider than an aperture in the housing (see Figures 13, 15 (below) and column 11, lines 17-20).

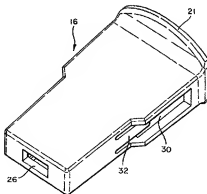


FIG. 15

In this configuration of MORITA, the projections are designed to prevent inadvertent premature removal of the cap and also to indicate whether the field between the cap and the needle is in tack. Much is made in MORITA of the fact that the cap is withdrawn axially, and indeed the wider projections 94 are designed to protect the cap from being twisted inadvertently (see column 12, lines 28-29).

When applying MORITA the Official Action suggests in paragraph 6 that the cap could be twisted while pulling. This runs entirely counter to the teachings of MORITA, which specifically provide the projections or stops to prevent the cover from being twisted. That is, MORITA teaches away from the present invention.

There is great emphasis played on the twist prevention feature in column 12, lines 31-44 of MORITA. Moreover, the design of MORITA is such that when the projections or stops are clear of the aperture 26 (thereby allowing the cap to be rotated) the cap will already have been detached from the lancet. In column 11, line 64 to column 12, line 3 the inventors explain that, when the first stops 92 and the second stops 94 are both exposed outside the cover it indicates that the resin cover may be broken (i.e. detached from the lancet).

In contrast, claim 1 requires that the cap is twistable to release the locating member on the cap from the cooperating feature on the housing such that the cap can be detached from the

housing and the lancet. Note that if the cap of MORITA has been pulled sufficiently far forward to take the projections clear of the housing, it will have already detached from the lancet and so the twisting will have no effect.

Thus, clearly in the arrangement of MORITA the entire device is designed so as to prevent the cap from being detached by twisting. In brief, the claimed device of the present invention is designed to allow detachment by twisting (alone) whereas MORITA is designed to allow detachment by an axial pull alone and specially designed to prevent twisting - the two concepts could not be more opposite in logic!

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Therefore, MORITA fails to anticipate a claimed embodiment of the present invention. One of ordinary skill and creativity would fail to produce a claimed embodiment of the present invention from a knowledge of MORITA, and a *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

**CONCLUSION**

Having addressed all the outstanding issues, the amendment is believed to be fully responsive. In view of the above, it is respectfully submitted that the application is in condition for allowance and notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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